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Application No. 10/736,493

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### REMARKS

Claims 1-17 are pending. Claims 8, 13, 16, and 17, which were withdrawn from consideration as the result of an Examiner's earlier restriction requirement, are canceled herein in the interests of advancing prosecution. In view of the Examiner's restriction requirement, Applicant reserves the right to present the above-identified canceled withdrawn claims in a divisional application.

Claims 7, 10, 12, and 15 are amended herein and claim 18 is added. Applicants disagree with all rejections and makes these claim changes only to expedite prosecution and move to allowance as soon as possible. Applicants submit that the amendments introduce no new matter (e.g. see [0054] and Figs. 8A, 8C, 8D). Upon entry of this paper, claims 7, 9-12, 14-15, and 18 will be pending and under consideration.

Favorable reconsideration in light of the remarks which follow is respectfully requested.

#### 1. Election/Restrictions

The Office notes that Applicant did not make an election on the "Stylet" group of species. Applicants submit that the presently pending claims do not recite a stylet. Reconsideration and withdrawal of this requirement is respectfully requested.

#### 2. Specification

Applicants have updated the "Cross-Reference to Related Applications" as requested. Reconsideration and withdrawal of this objection is respectfully requested.

#### 3. Claim Objections

Claims 7, 12, 12, and 15 are objected to. Applicants amend the claims herein as proposed. Reconsideration and withdrawal of this objection is respectfully requested.

#### 4. 35 U.S.C. 112 Rejections

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Claims 7, 9-12, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph. Applicants amend claim 7 herein as requested. Reconsideration and withdrawal of the rejection is respectfully requested.

#### 4. Double Patenting

Claims 7, 9-12, 14, and 15 are rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,685,745. A terminal disclaimer with respect to U.S. Patent No. 6,685,745 is filed herewith. Reconsideration and withdrawal of the rejection is respectfully requested.

#### 5. 35 U.S.C. 102 Rejections

##### *Devonco '209*

Claims 7 and 11 are rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,766,209 to Devonco (hereinafter "Devonco '209"). Applicants respectfully traverse.

Applicants recite, in amended claim 7, a prostatic stent for use in a patient comprising a first segment locatable on the proximal side of the patient's external urinary sphincter a second segment locatable on the distal side of the external urinary sphincter, and connecting segment disposed between the first and second segments and coupling together the first and second segments. The first segment includes an external surface, an internal surface, a proximal portion, a distal end, a lumen defined by the internal surface and extending within the first segment, a channel disposed between the external surface and the internal surface, and a plurality of openings in communication with the channel for conveying at least one agent to the external surface via the channel. The proximal portion of the first segment includes at least one opening in communication with the lumen for receiving fluid from the bladder of the patient. The distal end of the first segment terminates on the proximal side of the external urinary sphincter when the prostatic stent is placed within the body of the patient. The second segment is locatable on the distal side of the external urinary sphincter of the patient and includes an external surface, an internal surface, a proximal end, a distal end, and a lumen defined by the internal surface and extending within the second segment.

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The proximal end of the second segment terminates on the distal side of the external urinary sphincter when the prostatic stent is placed within the body of the patient.

An agent, such as a hemostatic agent or other active agent(s), can be provided to the external surface of the first segment by injecting the agent through the channel so that the agent flows through the channel, through the openings, and to the external surface.

Applicants respectfully submit that Devonec '209 at least does not teach or suggest a prostatic stent comprising a first segment including an external surface, an internal surface, a channel disposed between the external surface and the internal surface, and a plurality of openings for conveying at least one agent to the external surface via the channel.

With respect to Applicants' openings, the Office points to orifices (Fig. 6) and perforations 51 (Fig. 13). Applicants note that perforations 51 are provided to promote embedding of the prosthesis with respect to the urethral wall. However, nowhere in Devonec '209 is it taught or suggested that the stent is provided with a channel disposed between the external surface and the internal surface of the segments (i.e. within the walls of the segments) in communication with these orifices or perforations.

Accordingly, claim 7 is patentable over Devonec '209. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Devonec '209. Reconsideration and withdrawal of the rejections is respectfully requested.

#### *Tihon*

Claims 7 and 11 are rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,865,815 to Tihon (hereinafter "Tihon"). Applicants respectfully traverse.

Applicants respectfully submit that Tihon at least does not teach or suggest a prostatic stent comprising a first segment including an external surface, an internal surface, a channel disposed

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between the external surface and the internal surface, and a plurality of openings for conveying at least one agent to the external surface via the channel.

With respect to Applicants' openings, the Office points to bores 28. However nowhere in Tihon is it taught or suggested that the catheter is provided with a channel disposed between the external surface and the internal surface of the zones (i.e. within the walls of the zones) in communication with these bores.

Accordingly, claim 7 is patentable over Tihon. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Tihon. Reconsideration and withdrawal of the rejections is respectfully requested.

*Alt et al.*

Claims 1, 9, 11, and 14 are rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,788,979 to Alt et al. (hereinafter "Alt"). Applicants respectfully traverse.

Applicants respectfully submit that Alt at least does not teach or suggest a (i) prostatic stent comprising a first segment including an external surface, an internal surface, a channel disposed between the external surface and the internal surface, and a plurality of openings for conveying at least one agent to the external surface via the channel; (ii) a second segment; or (iii) a connecting segment disposed between the first and second segments and coupling together the first and second segments.

With respect to the plurality of openings, the Office points to Figures 3 and 5.

Figure 3 is an illustration of a balloon catheter 22 for performing balloon angioplasty to increase the diameter of the artery lumen (see col. 11, lines 12-22). A stent 25 can be implanted to maintain the lumen open either at the same time as the angioplasty (positioning the stent atop the balloon) or the stent can be implanted after angioplasty is finished (see col. 11, lines 23-37). Thus,

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Figure 3 refers to an angioplasty balloon and not a prosthetic stent. Further, nowhere does Figure 3 or the disclosure of Alt teach or suggest a plurality of openings or a channel disposed between the external surface and the internal surface of the balloon (i.e. within the walls of the balloon) in communication with openings in the balloon, a second segment, or a connecting segment disposed between the first ("balloon") and second segments and coupling together the first ("balloon") and second segments. Rather, Alt only shows a single segment (balloon).

Figure 5 is an illustration of a stent 25' having a plurality of coating layers 30, 31, 32, 33, 27. While Figure 5 appears to show openings, these openings are in the inner-most layer and are completely covered by the coating layers 30, 31, 32, 33, 27. As such, they are not in communication with the external surface for conveying at least one agent to the external surface. Further, nowhere in Alt is it taught or suggested that the stent is provided with a channel disposed between the external surface and the internal surface of the stent (i.e. within the walls of the stent) in communication with these openings. Still further, nowhere does Figure 5 or the disclosure of Alt teach or suggest, a second segment, or a connecting segment disposed between a first and second segments and coupling together the first and second segments. Rather, Alt only shows a single segment (stent 25').

Accordingly, claim 7 is patentable over Alt. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Tihon. Reconsideration and withdrawal of the rejections is respectfully requested.

*Devonec '368*

Claim 7 is rejected under 35 U.S.C. 102(b) over U.S. Patent No. 6,238,368 to Devonec (hereinafter "Devonec '368"). Applicants respectfully traverse.

Applicants respectfully submit that Devonec '368 at least does not teach or suggest a prosthetic stent comprising a first segment including an external surface, an internal surface, a

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channel disposed between the external surface and the internal surface, and a plurality of openings in communication with the channel for conveying at least one agent to the external surface via the channel.

While Devonce '368 describes perforations 13 for ensuring the passage of urine from the bladder (col. 6, lines 46-48) and channels 9 to promote the passage of bodily liquids or secretions, nowhere in Devonce '368 is it taught or suggested that the device is provided with a channel disposed between the external surface and the internal surface of the device (i.e. within the walls of the device) in communication with these perforations or channels.

Accordingly, claim 7 is patentable over Devonce '368. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Devonce '368. Reconsideration and withdrawal of the rejections is respectfully requested.

#### 6. 35 U.S.C. 103 Rejections

##### *Devonce '209 and Donovan*

Claims 9, 10, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) over Devonce '209 and U.S. Patent No. 5,833,651 to Donovan et al. (hereinafter "Donovan"). Applicants respectfully traverse.

As set forth above, Devonce '209 at least does not teach or suggest a prostatic stent comprising a first segment including an external surface, an internal surface, a channel disposed between the external surface and the internal surface, and a plurality of openings for conveying at least one agent to the external surface via the channel.

Donovan does not remedy these deficiencies in Devonce '209. Donovan is cited for describing stents with particular coatings. However, nowhere in Donovan are openings or channels taught or even suggested.

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Accordingly, claim 7 is patentable over Devonce '209 and Donovan. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Devonce '209 and Donovan. Reconsideration and withdrawal of the rejections is respectfully requested.

*Alt*

Claims 10, 12, and 15 are rejected under 35 U.S.C. 103(a) over Alt. Applicants respectfully traverse.

As set forth above, Alt at least does not teach or suggest a (i) prostatic stent comprising a first segment including an external surface, an internal surface, a channel disposed between the external surface and the internal surface, and a plurality of openings for conveying at least one agent to the external surface via the channel; (ii) a second segment; or (iii) a connecting segment disposed between the first and second segments and coupling together the first and second segments.

While Alt describes a stent 25' in connection with Figure 5, which appears to show openings, the stent 25' has a plurality of coating layers 30, 31, 32, 33, 27 which completely cover the openings on the inner-most layer. Thus, these openings are not in communication with the external surface for conveying at least one agent to the external surface. Further, nowhere in Alt is it taught or suggested that the stent is provided with a channel disposed between the external surface and the internal surface of the stent (i.e. within the walls of the stent) in communication with these openings. Still further, nowhere does Figure 5 or the disclosure of Alt teach or suggest, a second segment, or a connecting segment disposed between a first and second segments and coupling together the first and second segments. Rather, Alt only shows a single segment.

Accordingly, claim 7 is patentable over Alt. Claims 9-12, 14-15 and 18 depend from claim 7 and likewise, are patentable over Tihon. Reconsideration and withdrawal of the rejections is respectfully requested.

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Dated: February 14, 2007

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